DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions, Inc.
% Ms. Patricia Jones
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

February 24, 2015

Re: K143319
Trade/Device Name: syngo X-Workplace SW VD10
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 29, 2015
Received: January 30, 2015

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143319

Device Name

syngo X-Workplace SW VD10

Indications for Use *(Describe)*

The syngo X Workplace is a medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The syngo X Workplace can be configured as stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, the X Workplace can be combined with systems of the Artis family. In combination with an Artis system, it provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The syngo X Workplace can also be combined with fluoroscopy systems or Radiographic systems.

The syngo X Workplace can be configured with a variety of syngo or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: *syngo* X Workplace

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: November 18, 2014

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Solutions, USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name:	*syngo* X Workplace SW VD10
Classification Name:	Picture Archiving and Communications system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	LLZ

4. Legally Marketed Predicate Device

Trade Name:	X-LEONARDO Workstation
510(k) Clearance	K042995
Clearance Date	November 24, 2004
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This predicate device has not been the subject of any design related recalls.

5. Device Description:

SIEMENS Medical Solutions USA, Inc. intends to market the *syngo* X Workplace (XWP), SW Version VD10. This 510(k) submission describes several modifications to the previously cleared predicate device the X-LEONARDO Workstation (K042995) cleared on November 24, 2004. The modifications were made to the cleared X-LEONARDO Workstation SW VC10 that created the *syngo* X Workplace (XWP), SW Version VD10:

1). Updated Indications for Use Statement:
2). Updated Operating system, Windows 7
3). Updated SW version VD10 includes the following software features:
- New 4D-Viewer
  - QuickZoom
  - *syngo* Dyna4D
  - 3D Wizard
  - *syngo* 2D/3D fusion
  - *syngo* DynaCT SMART
  - Dedicated graphical User Interface for the examination room

4). Image Archiving on Blu-Ray Disc, optional
5). Proposed product claims associated with the above device modifications (see **Section 15**)
6) Provides update 510(k) information (see **Appendix E**).

The X Workplace is a medical diagnostic workstation for real-time viewing, image manipulation, communication, and storage of medical images and data on exchange media.

The X Workplace is a further development of the X-LEONARDO Workstation. The X Workplace offers a comprehensive solution to view, optimize, and post-process diagnostic information and to aid the doctors in the evaluation of digital radiological examinations and patient information.

Due to special customer requirements based on the modality image type and the clinical focus, the X Workplace can be configured with different combinations of clinical applications. Applications can be added to the X Workplace either individually or as clinical focus packages.

The X Workplace can be configured with a variety of *syngo*- or Windows based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available OEM applications.

The *syngo* X Workplace (XWP) is within the same classification regulation, but with a more descriptive indication for use from the primary predicate device; however the intended use and the general Indications for Use Statement for Siemens' Picture Archiving and Communications System remains the same.

Provided in **Sections 5 and 14** of this 510(k) submission, is a completed "510(k) Decision Making FlowChart". We believe these modifications are eligible for the Traditional 510(k) process since the subject device has the same fundamental scientific technology, Intended Use and general Indications for Use as the predicate device system. The new descriptive Indications for Use statement is supported with non-clinical testing in support of a claim of substantial equivalence to Siemens' predicate device the X-LEONARDO Workstation (K042995).

6. Indications for Use:

The X Workplace is a medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The *syngo* X Workplace can be configured as stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, the X Workplace can be combined with systems of the Artis family. In combination with an Artis system, it provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The *syngo* X Workplace can also be combined with fluoroscopy systems or Radiographic systems.

The *syngo* X Workplace can be configured with a variety of *syngo* or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The *syngo* X Workplace offers a comprehensive solution to view, optimize, and post-process diagnostic information and can be configured with different applications. These *syngo* applications can be added to the *syngo* X Workplace either individually or as clinical focus packages. For the viewing of 3D image data the Inspace viewer of the predicate device X-Leonardo is replaced with a new *syngo* 4D viewer.

The subject device (*syngo* X Workplace) is comparable to general Indications for Use for medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. The subject device has the same intended use, design, material, functionality, technology, energy source and is considered substantially equivalent to the commercially available Siemens' X-Leonardo workstation.

The components of the subject device have many of the same technological characteristics as the one from the predicate device. There are several technological characteristics that differ slightly as shown in the comparison table below which summarizes differences betwwen the Subject Device and Legally Marketed Predicate device:

Table 1: Predicate and Subject Device Compared Technological Characteristics

Technological Characteristics of the Subject Device as Compared with the Predicate Device:		
Property	**Subject Device: *syngo* X Workplace SW VD10**	**Predicate Device: X-Leonardo SW VC10**
New Operating System	**Updated Operating system Windows 7**	**Operating system Windows XP**
New SW VD10 / SW Applications	**New *syngo* 4D viewer:**	**InSpace viewer (K042995):**
	Quick Zoom – one button	**Zoom with mouse interactions**
	syngo Dyna4D - 3D rotational angiography with Improved angulation range	**InSpace 3D rotational angiography**
	3D Wizard - Electronic Protocol book	**Printed protocol book Manual selection of organ program**
	syngo DynaCT S.M.A.R.T.	**syngo DynaCT**
	Dedicated Graphical User Interface	**1:1 mirroring of control room display in examination room**
	***syngo* 2/D/3D Fusion**	**3D/3D registration based on *syngo* InSpace 3D/3D Fusion**
Image Archiving	**Archiving Blu-Ray disc**	**Archiving DVD**

The subject device (*syngo* X Workplace) modifications do not alter its fundamental scientific technology from the 510(k) cleared predicate device

Siemens' X-Leonardo workstation. The interface/usability has been optimized to improve clinical workflows.

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the *syngo* X Workplace during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. and provided clinical images.

Siemens claims conformance to the following performance standards: 60950-1+A1; 94 A/B; 60601-1-2; 14971; 60601-1-6; 62304; 60038; CAN 7CSA-C22.2 No. 60950-1-08; NEMA PS3 and following / ISO 12052 as provided in **Section 11.**

Verification and Validation:

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (**Section 21)** were conducted on the *syngo* X Workplace during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Siemens conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Contained in **Attachment 8** of this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 8001-1-2010 is the hospital. Provided in the Software section, (**Section 18**) and the Operator's Manual (**Appendix B**) is the required cybersecurity information.

Summary:

Performance tests were conducted to test the functionality of the *syngo* X Workplace workstation. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing and clinical images were found acceptable in supporting the claim of substantial equivalence.

9. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of medical images.

10. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information and clinical images. The results of these tests demonstrate that *syngo* X-Workplace acceptance criteria are adequate for this intended use. The comparison of technological characteristic, non-clinical performance data, clinical images, and software validation data demonstrates that the subject device is as safe, and effective when compared to the predicate device that is currently marketed for the same intended use.

.